REMARKS

Claims 1-14 are extant in the present prosecution.

REJECTION UNDER 35 USC §102(B)

Claims 7, 9, and 10 are not anticipated under 35 USC §102(b) by Cherukuri et al. (US 4,931,293). To anticipate a claim, each and every element as set forth in the claim must be found, either expressly or inherently described, in the prior art reference (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987)).

In the present case, Cherukuri does not include a hydrophilic additive in the coating. Though the *coating mixture* is said to have "*sufficient* hydrophilic character," Cherukuri also states that it is "*substantially* poorly water soluble" (col.5:47-51, emphasis supplied). Applicants submit that something "substantially" insoluble in water cannot be considered "hydrophilic." Further, Cherukuri's description of the overall hydrophobicity of the coating mixture *does not* necessarily apply to one or the other ingredients, without further explanation than the examiner has supplied.

Additionally, Cherukuri does not teach a dosage form in which an active ingredient-containing core is coated with the polyvinyl acetate mixture. Rather, the polyvinyl acetate and the emulsifier are melted and mixed to homogeneity, with subsequent addition and mixing of the milled acid powder (col.5:66-col.6-8). This results in a "coating matrix" wherein the acid is embedded within the polyvinyl acetate mixture (col.6:26).

maintain

Cherukuri does not teach the above elements of the presently claimed invention, and therefore cannot anticipate the present invention under 35 USC §102(b). Accordingly, applicants respectfully request that the rejection of claims 7, 9, and 10 be withdrawn.

REJECTION UNDER 35 USC §103(A)

Claims 7-13 are not obvious under 35 USC §103(a) over Cherukuri (above) in view of Khankari et al. (US 6,221,392). To establish *prima facie* obviousness, the examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*see, e.g., In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

As discussed above, Cherukuri discloses neither the combination of polyvinyl acetate with a hydrophilic additive, nor the coating of an active ingredient-containing core. Further, this reference neither suggests nor gives motivation for inclusion of these elements. The disclosure of Khankari is likewise silent on these points.

The intended result of Cherukuri is to provide a relatively rapid release of the active ingredient in the individual's mouth. As indicated therein, 40% of the active ingredient is released after 2 minutes of mastication, and such results would be insufficient for purposes of taste-masking. Addition of a hydrophilic substance to the mixture of Cherukuri would prevent release of the active ingredient for the entire time in which the dosage form

remains in the individual's mouth. This would make the invention disclosed by Cherukuri ineffective for its intended purpose. Such a result argues against *prima facie* obviousness (*see, e.g., In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Khankari is cited for its disclosure of a disintegrant, in particular, a wicking agent. However, the addition of such a compound to the polyvinyl acetate mixture of Cherukuri would only serve to enhance the rate at which the active ingredient is released in the individual's mouth. Though this would further the purpose disclosed by Cherukuri, it would not achieve the results described in the present specification.

As neither Cherukuri nor Khankari suggest or give motivation for the inclusion of hydrophilic additives in the polyvinyl acetate mixture, and as addition of such hydrophilic compounds would make these inventions unsuitable for their intended purposes, the presently claimed invention cannot be made obvious thereby under 35 USC §103(a). Accordingly, applicants respectfully request that the rejection of claims 7-13 under this section be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

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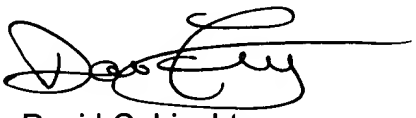
Respectfully submitted,

KEIL & WEINKAUF



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